K022217

OCT 2 4 2002

510(k) Summary

Contact: Grant Ramaley

Date Prepared: May 23, 2002

Trade or Proprietary Name: Transport II - Model Number: AEU-425
Portable Electronic Dental Operative System

Classification Name: Dental Operative Unit (872.6640)

Description of Transport II's characteristics

Portable Electrical Dental System that combine an autoclavable micro motor, dental irrigation, high and low volume suction and *Ultrasonic scaler into a single transportable carrying case into which all features have been integrated.

Features

1) Low voltage electric handpiece motor with forward, reverse and speed control.
    a. More powerful electric Handpiece motor offers more torque and runs cooler than previous models.
    b. Uses the same methods for powering and connecting contra angles used in the previously marketed devices covered by Aseptico's previous approval under K882526/A
    c. The electrical and mechanical safety of the handpiece drive system complies with IEC 601.1 and is to be Classified under the U.S. version of Underwriters Laboratories UL 2601.1 – This product is tested and listed under UL File number E208087.
    d. The motor is designed so that the exterior surface can be sterilized in a steam autoclave between each patient use.
2) Irrigation and suction.
    a. The irrigation and suction systems employed by the AEU-425 are substantially equivalent to the previously marketed device "Asepti-mini" ADU-10 covered by 510(k) K905401.
    b. All water, waste water lines are made of polyethylene or polyurethane. Containers are made form either PET or Polyproplyene. All materials are commonly used in similar dental applications and are able to be disinfected using common bleach/water rinsing without suffering deterioration.
3) *Can be provided with an Ultrasonic Scaler.

***The optional ultrasonic Scaler is provided with all accompanying labels and instructions for use that are part of the original manufacturer's packaging . Any scaler sold with the Transport II is additionally evaluated along with the entire system by Underwriter's Laboratories to internationally recognized safety standards for medical devices (ref UL 2601.1).**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Mr. Grant Ramaley
Quality Assurance and Regulatory Affairs
Aseptico, Incorporated
8333 216th Street S.E.
Woodinville, Washington 98072

Re: K022217
Trade/Device Name: Transport II Model Number AEU-425 Portable Electronic Dental Operative System
Regulation Number: 872.6640 and 872.4200
Regulation Name: Dental Operative Unit and Accessories and Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EIA and EKX
Dated: October 10, 2002
Received: October 10, 2002

Dear Mr. Ramsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022217

Page_____of_____

510(k) Number (if known)

Device Name: Transport II Model Number AEU-425
Portable Electronic Dental Operative System

Indications For Use:

Transport II offers the dental professional the capability of carrying a complete dental operative system in one transportable case. The system is ideally suited for performing general dental procedures anywhere there is a suitable power source.

K Beltz DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K022217

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Countern Use_____
(Per CFR 801.109)

(Optional Format 1-2-96)